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Chin et al.

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(45) **Date of Patent: Feb. 12, 2013**

(54) **SPINOUS PROCESS FIXATION IMPLANT**

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(22) Filed: **Dec. 11, 2009**

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Related U.S. Application Data

(63) Continuation-in-part of application No. 11/609,418, filed on Dec. 12, 2006.

(51) **Int. Cl.**
A61B 17/70 (2006.01)

(52) **U.S. Cl.** **606/249**; 606/279

(58) **Field of Classification Search** 606/248, 606/249
See application file for complete search history.

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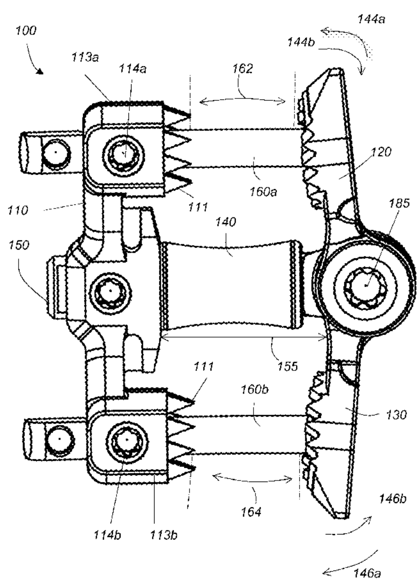
(57) **ABSTRACT**

An implantable spinous process fixation device includes an elongated component, top and bottom pivoting wing components, arranged opposite and parallel to the elongated component and separated from it by a spacer. First and second spinous processes of first and second adjacent vertebras are clamped between a top portion of the elongated component and the top pivoting wing and between a bottom portion of the elongated component and the bottom pivoting wing, respectively, by pivoting the top and bottom pivoting wings toward the top and bottom portions of the elongated component. The clamping of the spinous processes stabilizes the positions of the adjacent vertebras and prevents them from moving relative to each other.

17 Claims, 22 Drawing Sheets



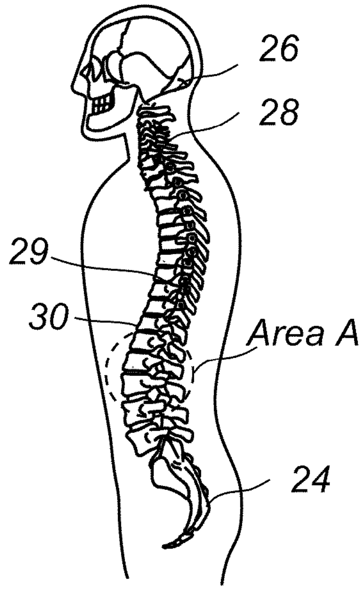


FIG. 1A

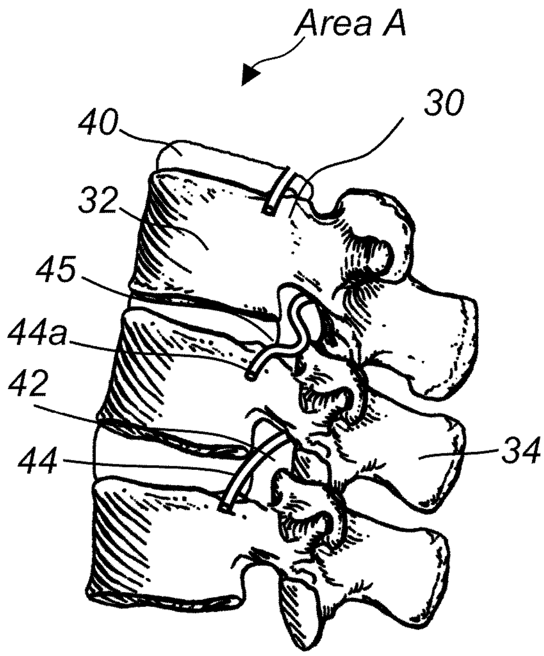


FIG. 1B

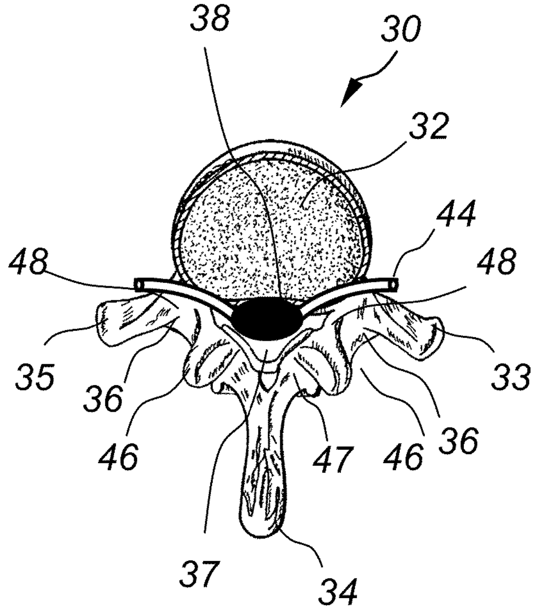


FIG. 1C

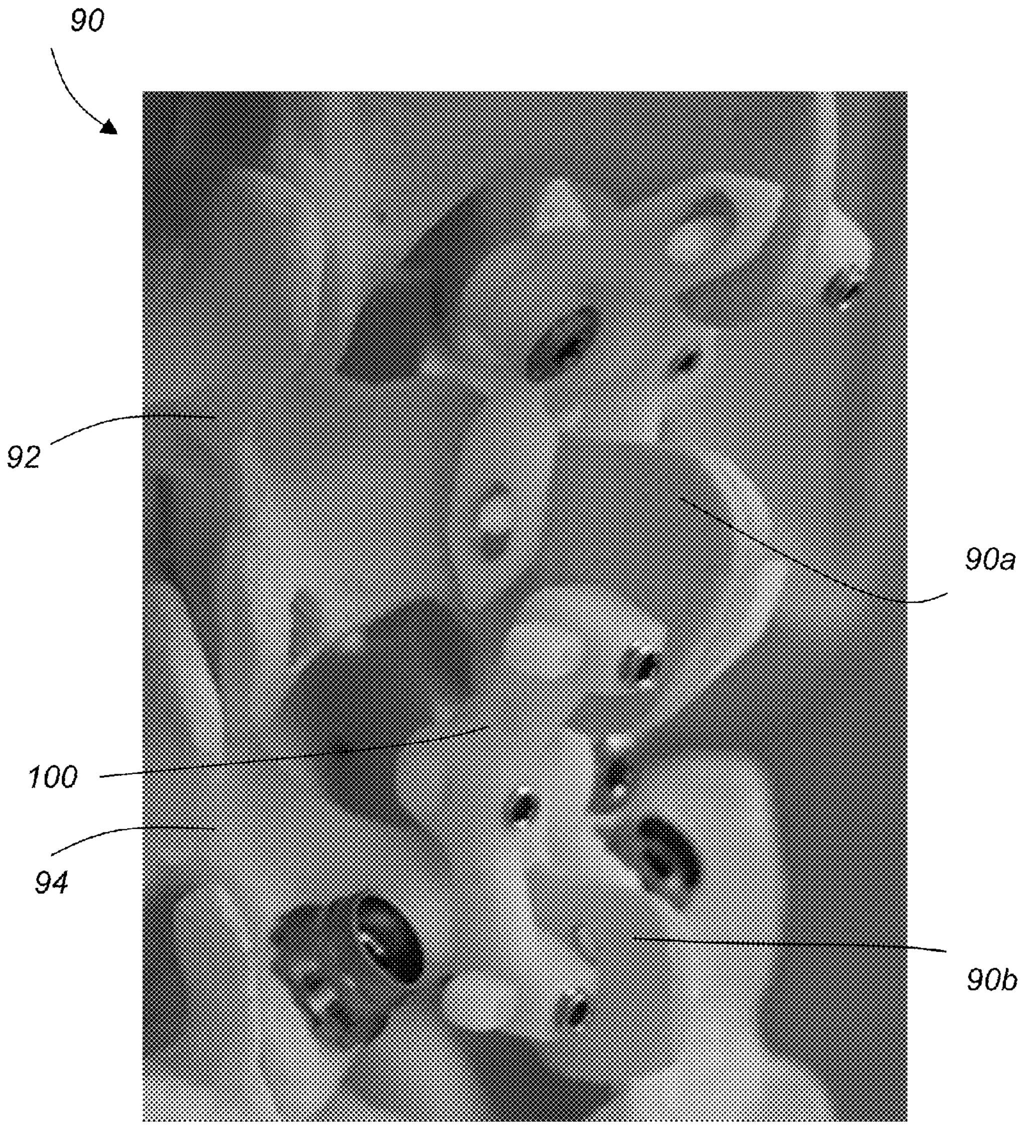
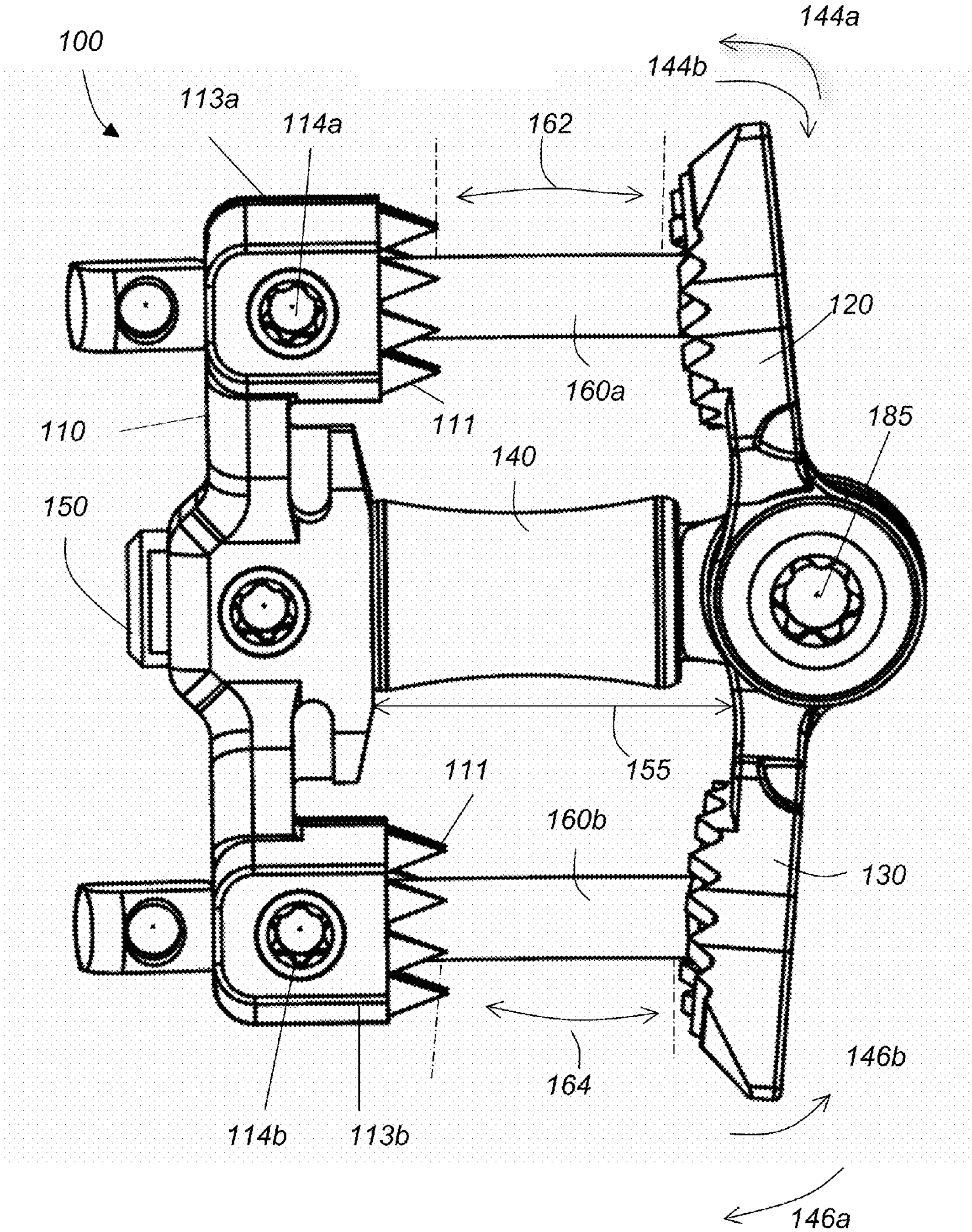


FIG. 2



100
113a
114a
162
144a
144b
120
160a
111
185
110
140
150
155
111
160b
130
164
146b
114b
113b
146a

FIG. 3

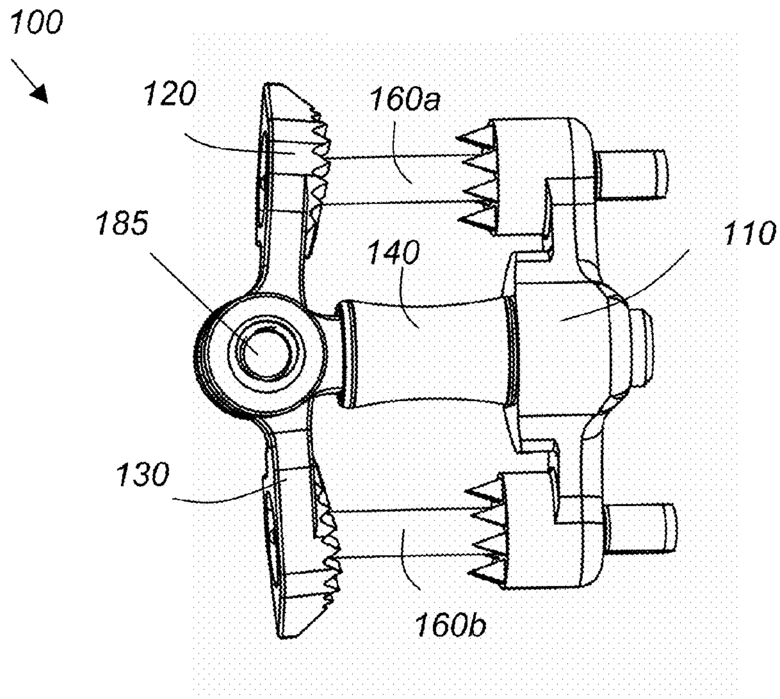


FIG. 4

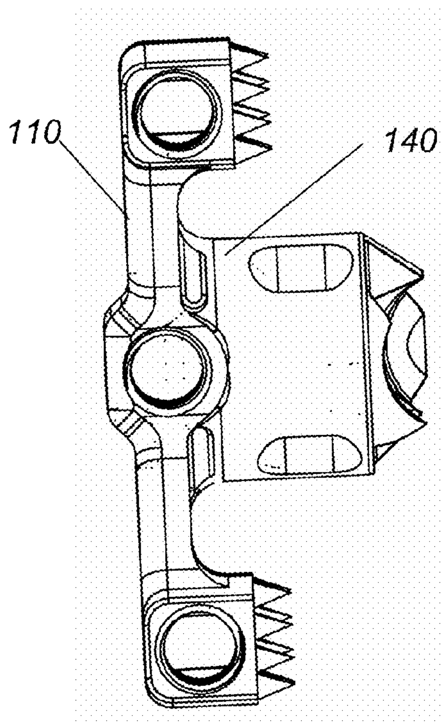


FIG. 5A

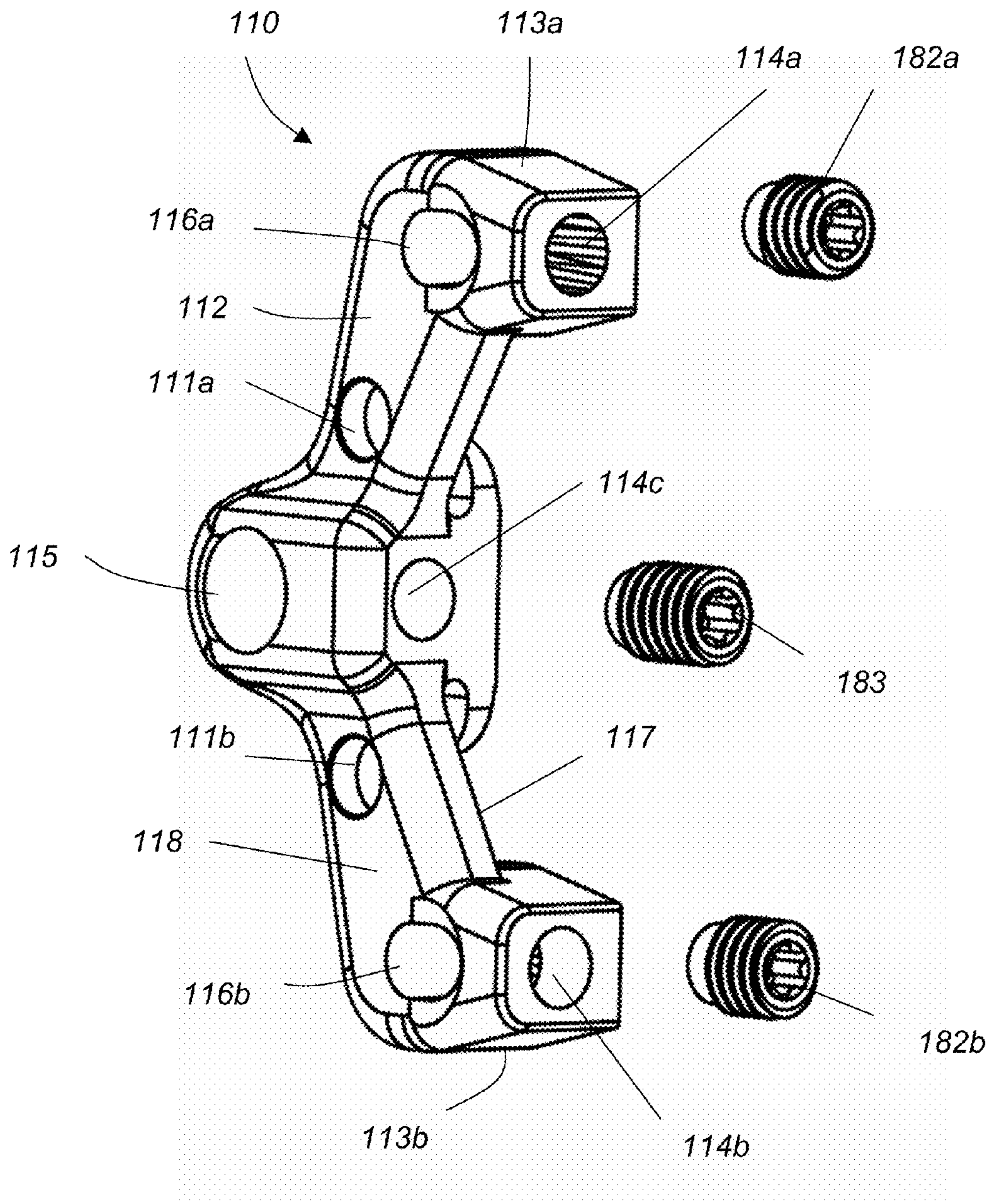
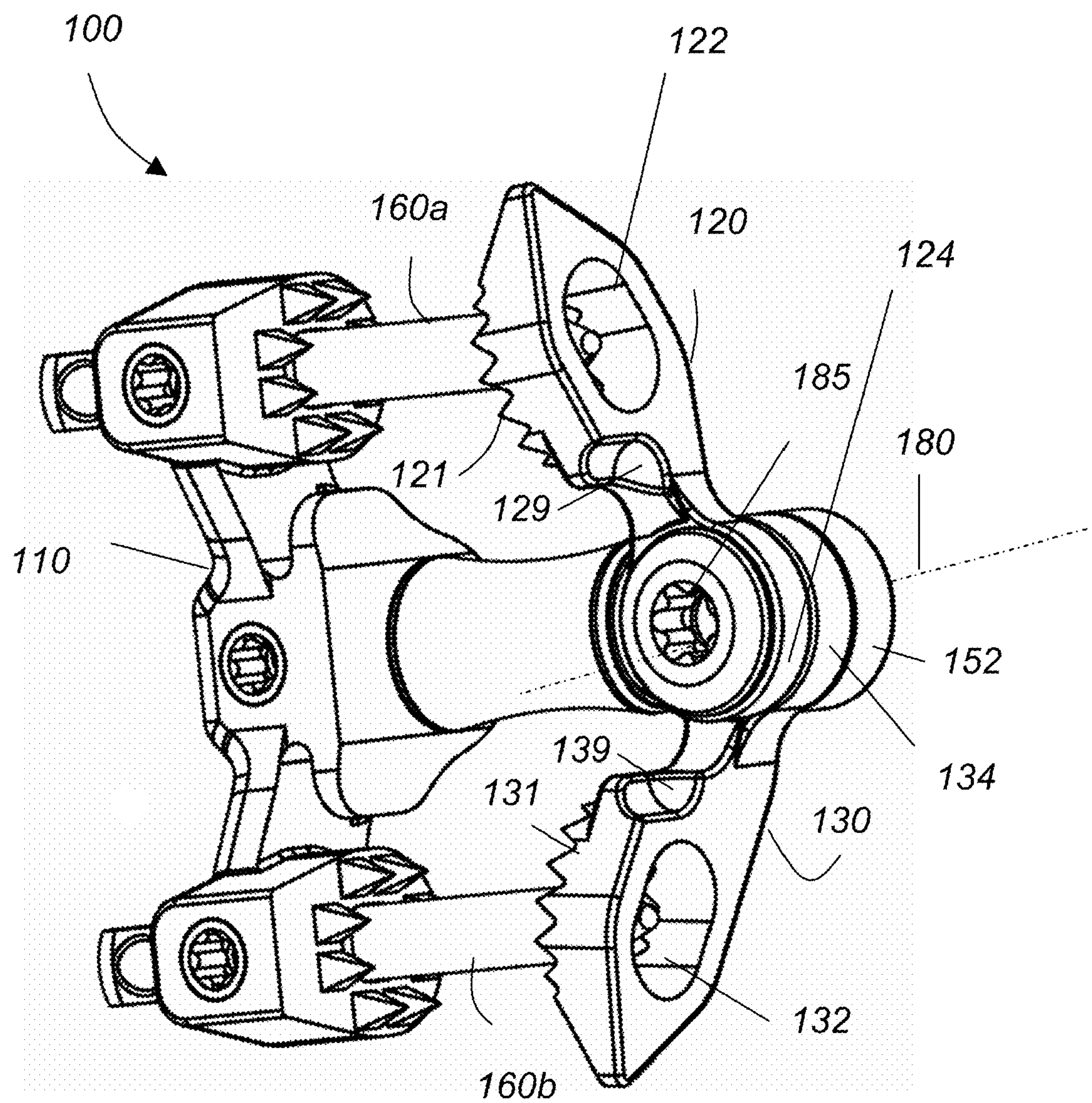

110
113a
114a
182a
116a
112
111a
114c
115
183
111b
117
118
116b
182b
113b
114b

FIG. 5


100
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160a
120
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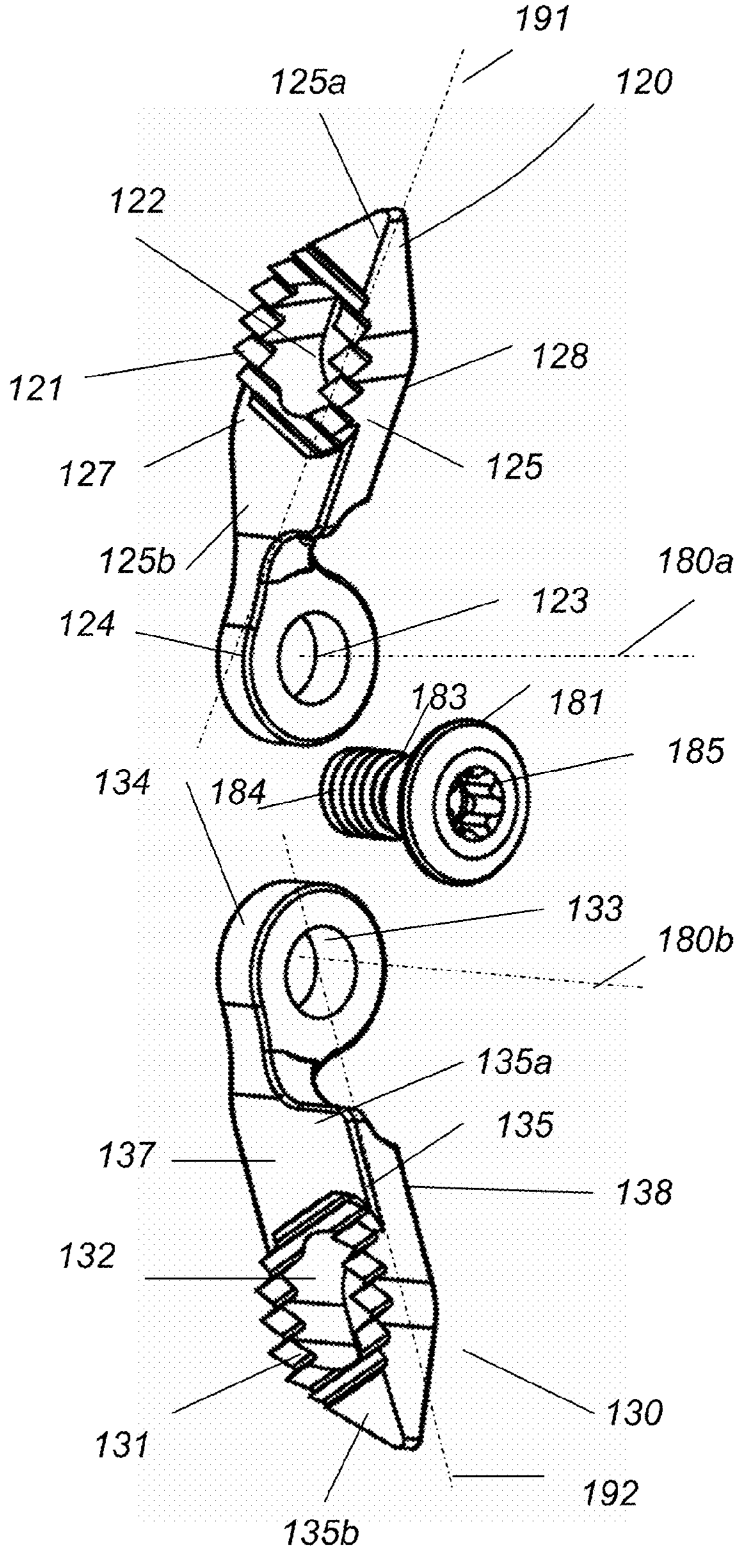
185
180
121
129
110
152
139
134
131
130
132
160b

FIG. 6


191
125a
120
122
121
128
127
125
125b
180a
124
123
183
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184
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180b
135a
135
137
138
132
130
131
192
135b

FIG. 7

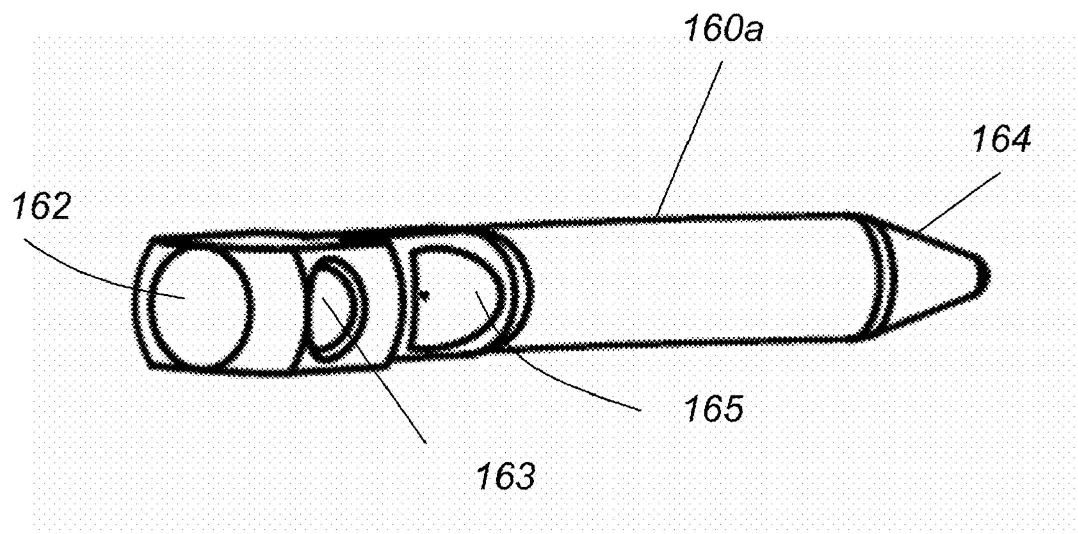

FIG. 8C

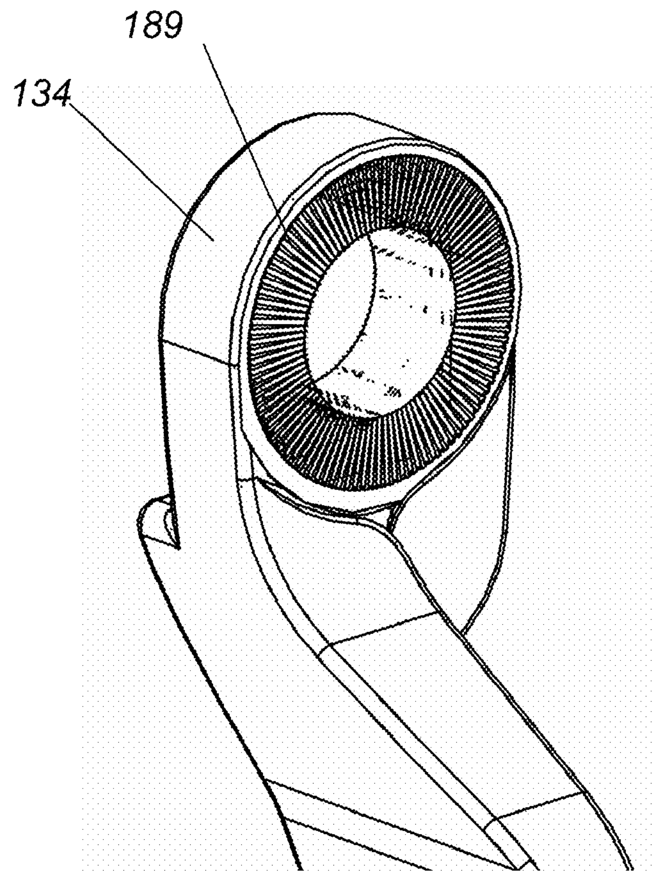

FIG. 7A

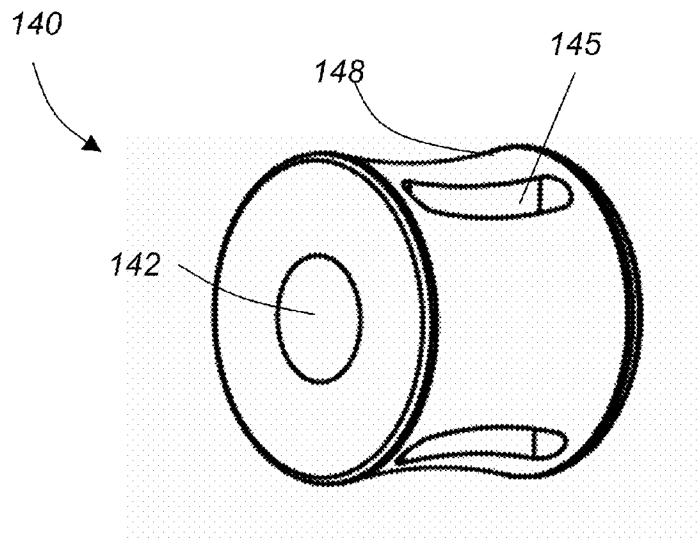

FIG. 8A

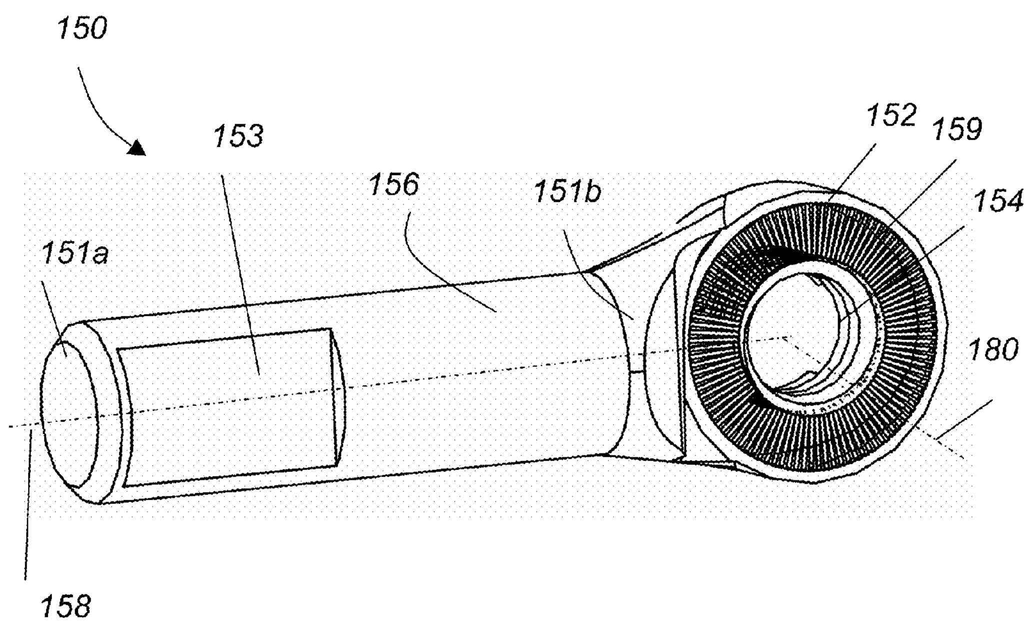

FIG. 8B

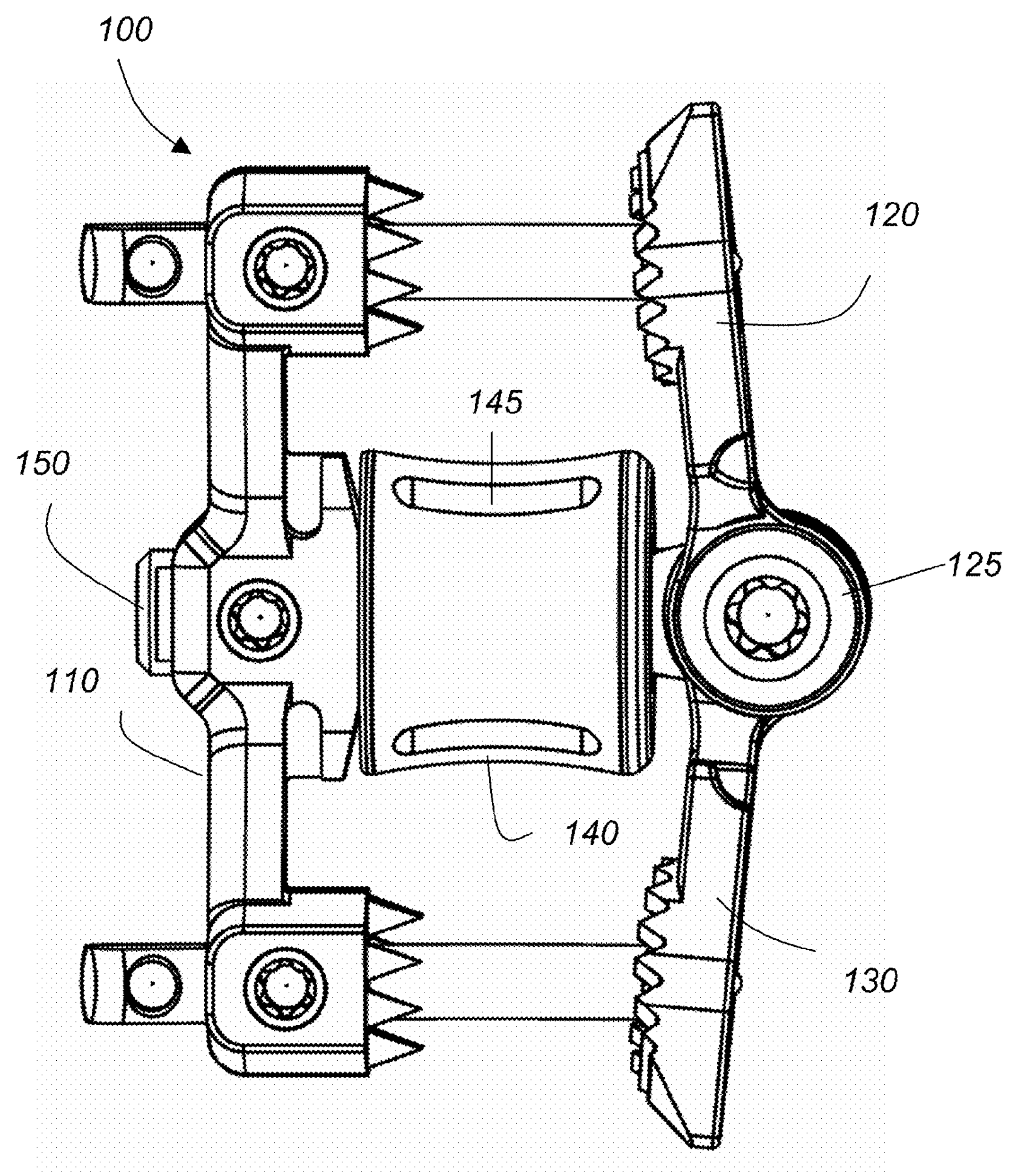

FIG. 9

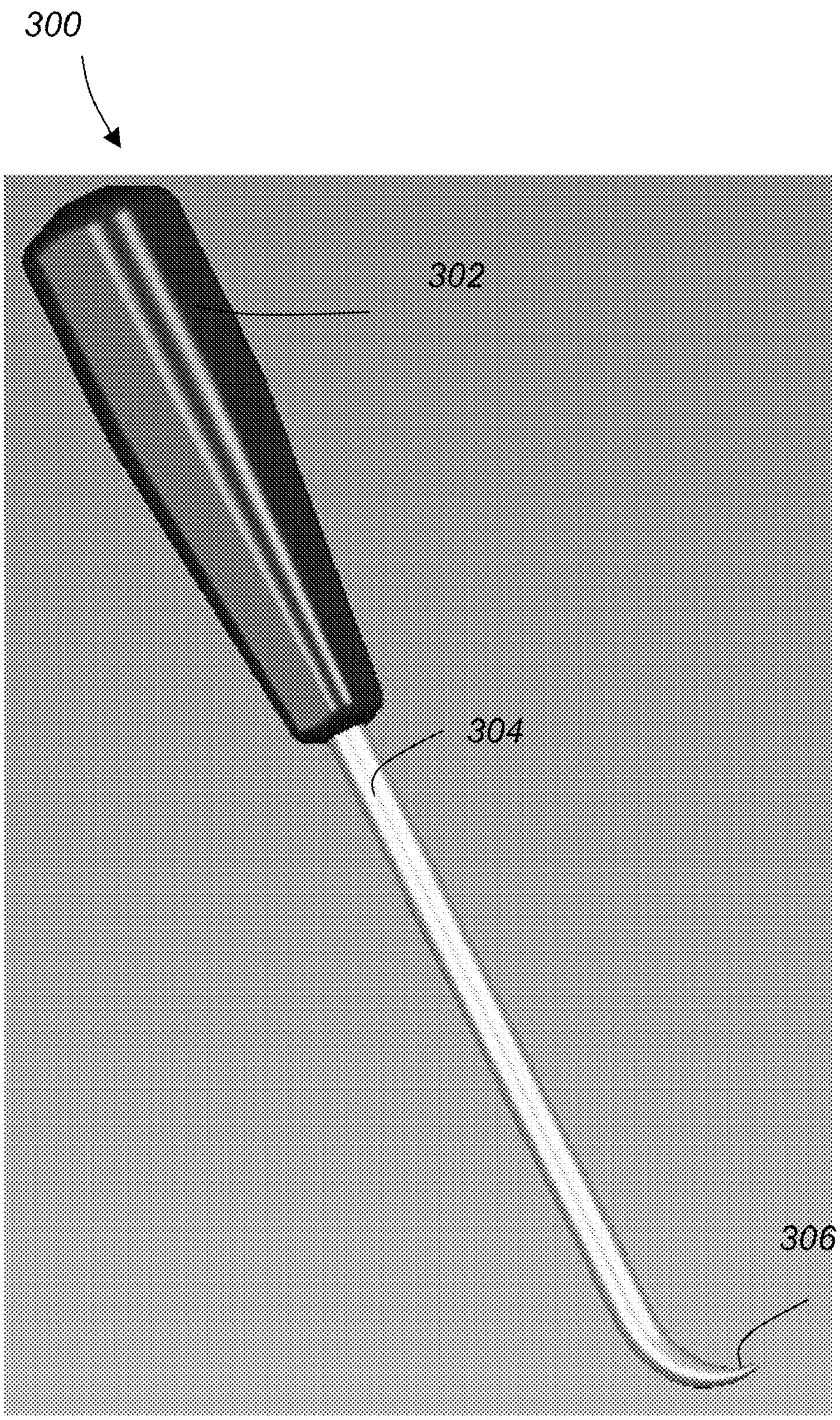

FIG. 10

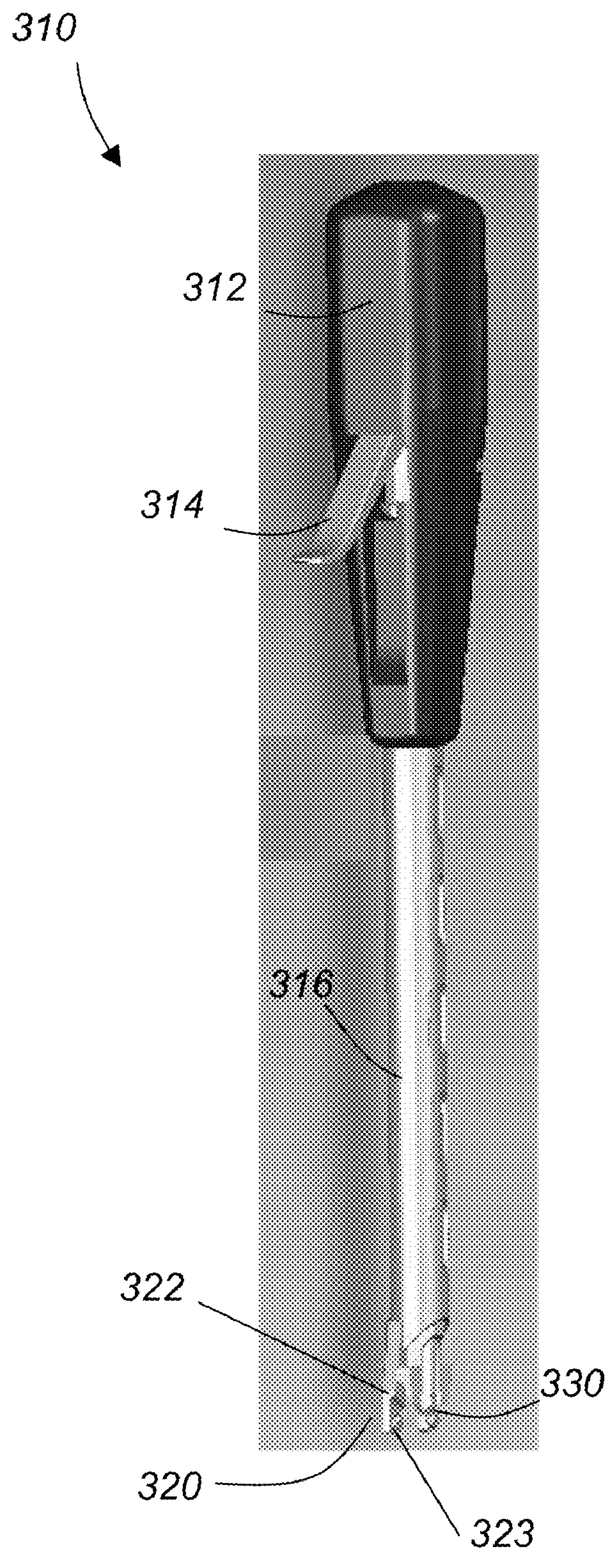

FIG. 11

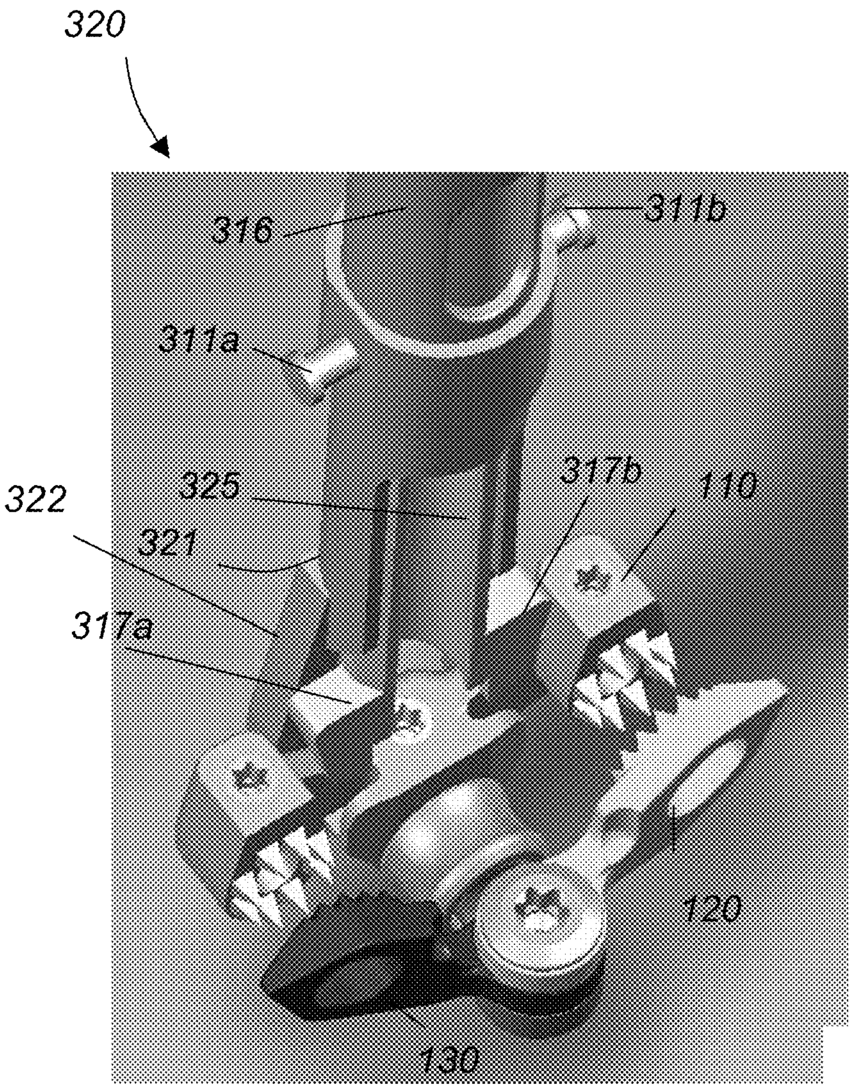

FIG. 12

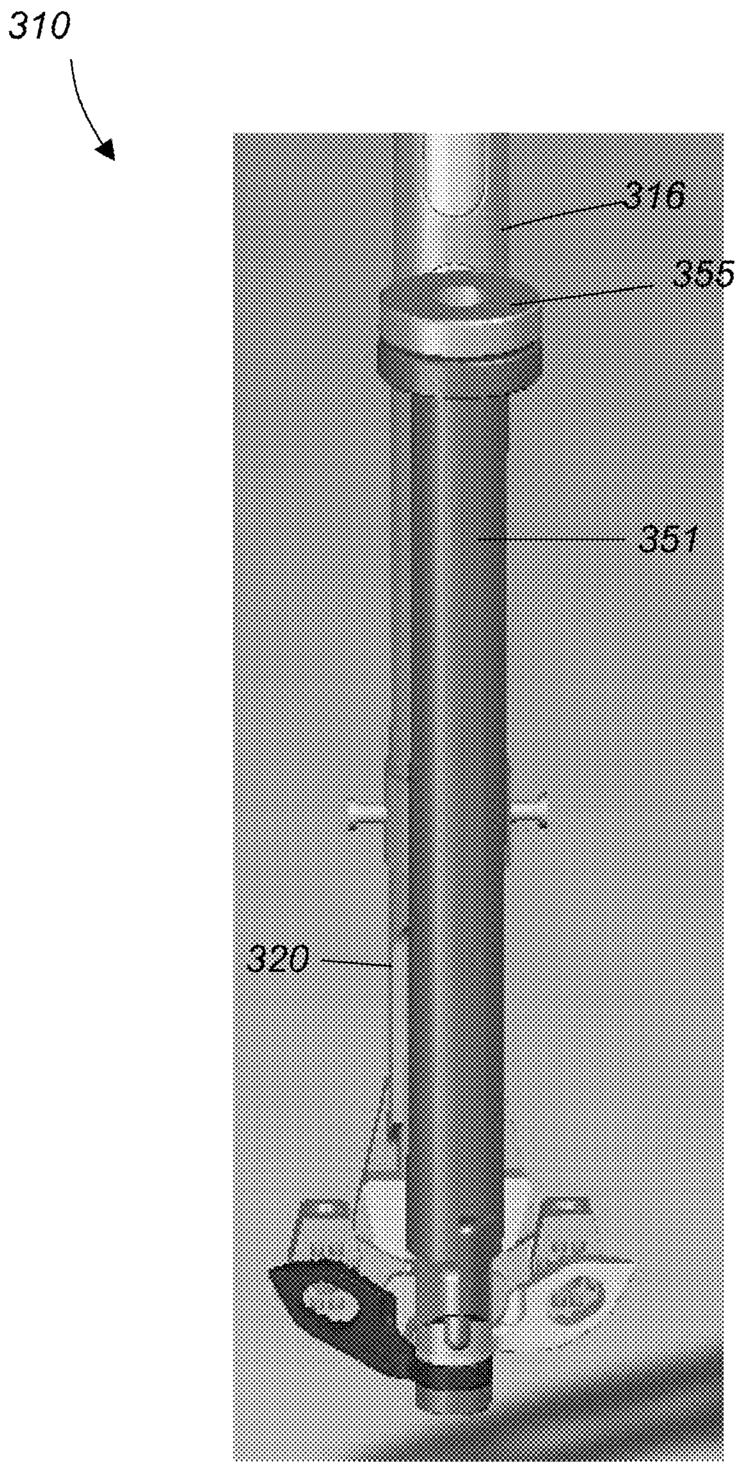

FIG. 13

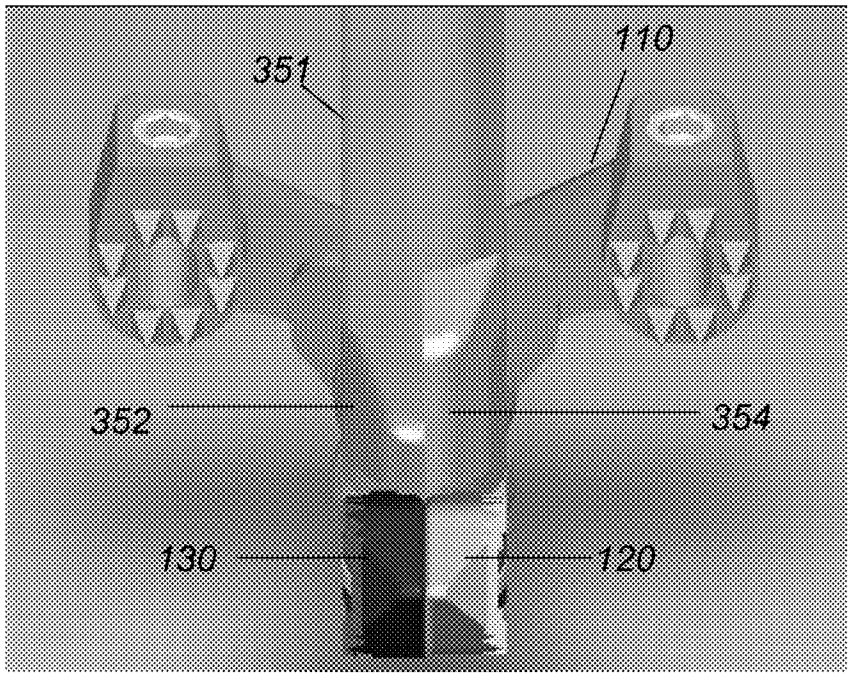

FIG. 14A

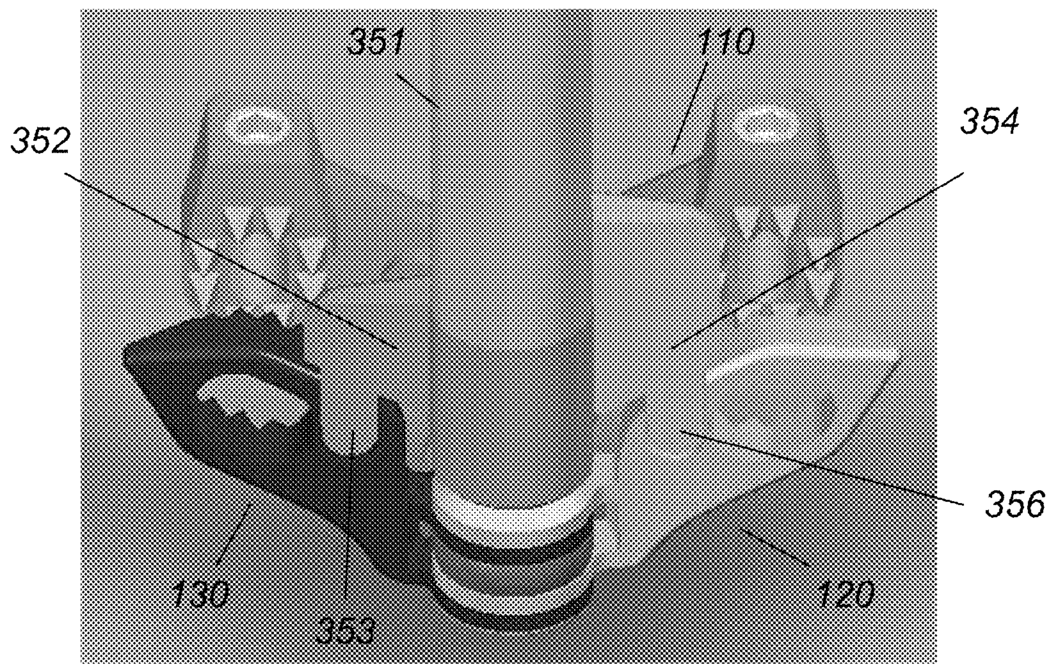

FIG. 14B

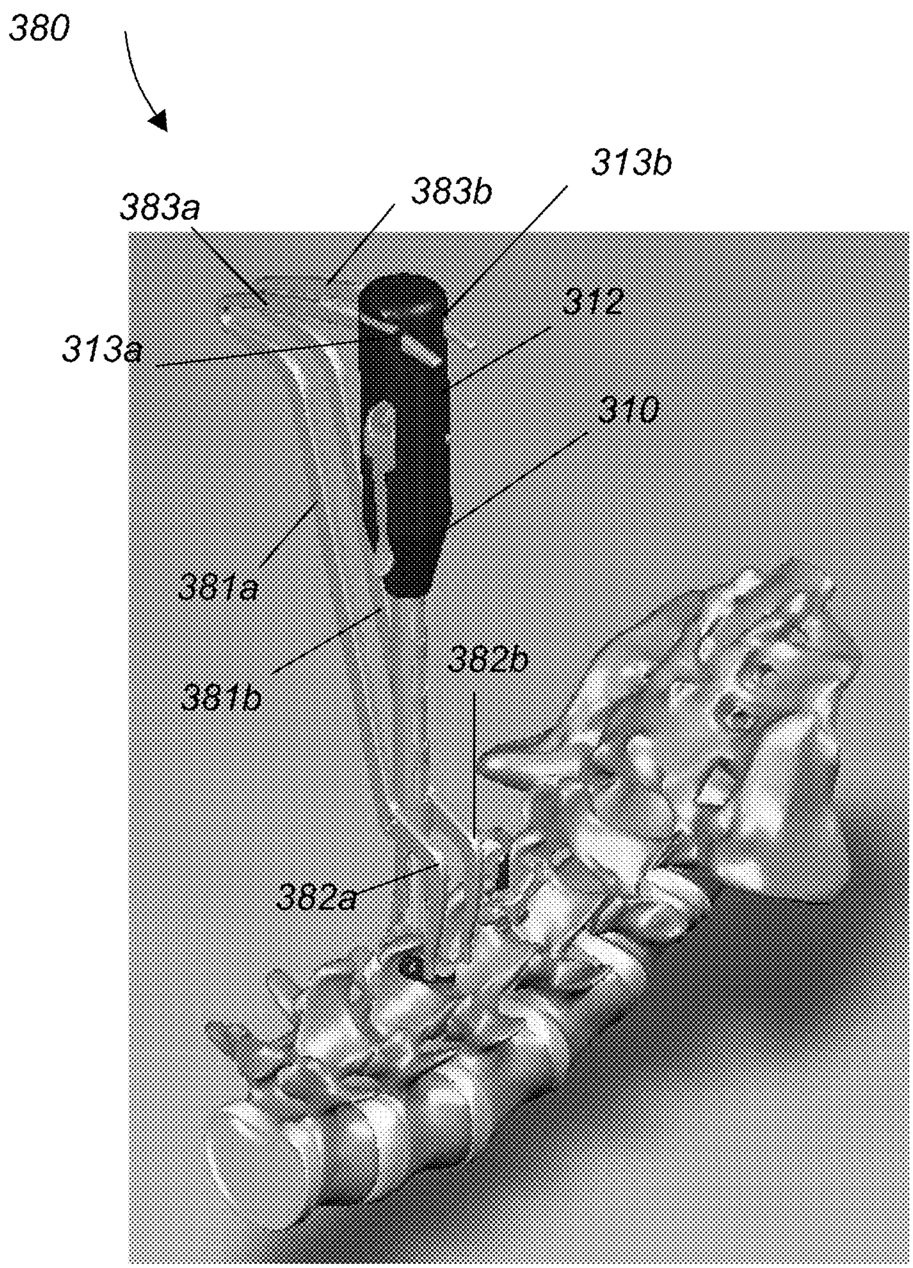

FIG. 15

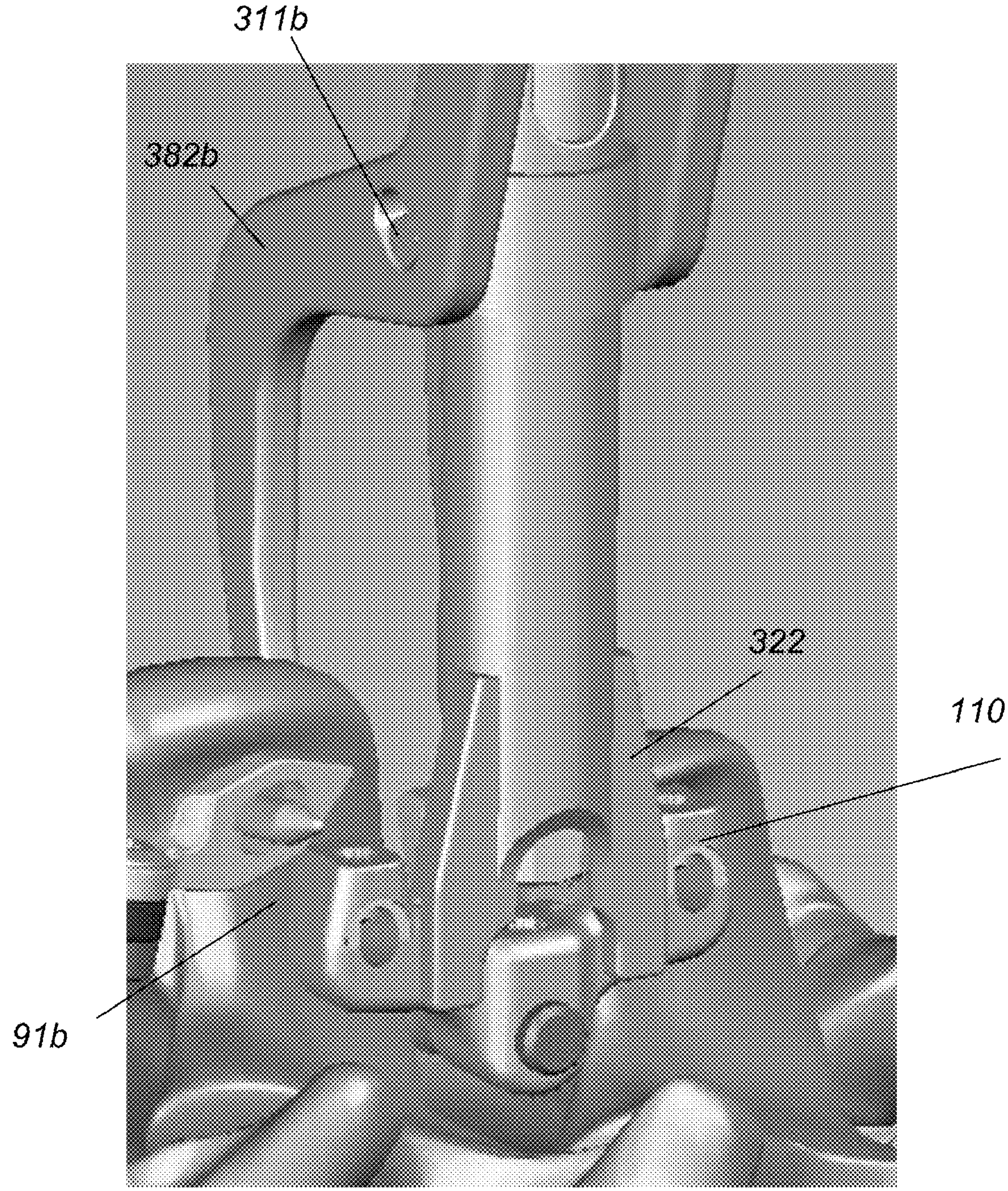

FIG. 16

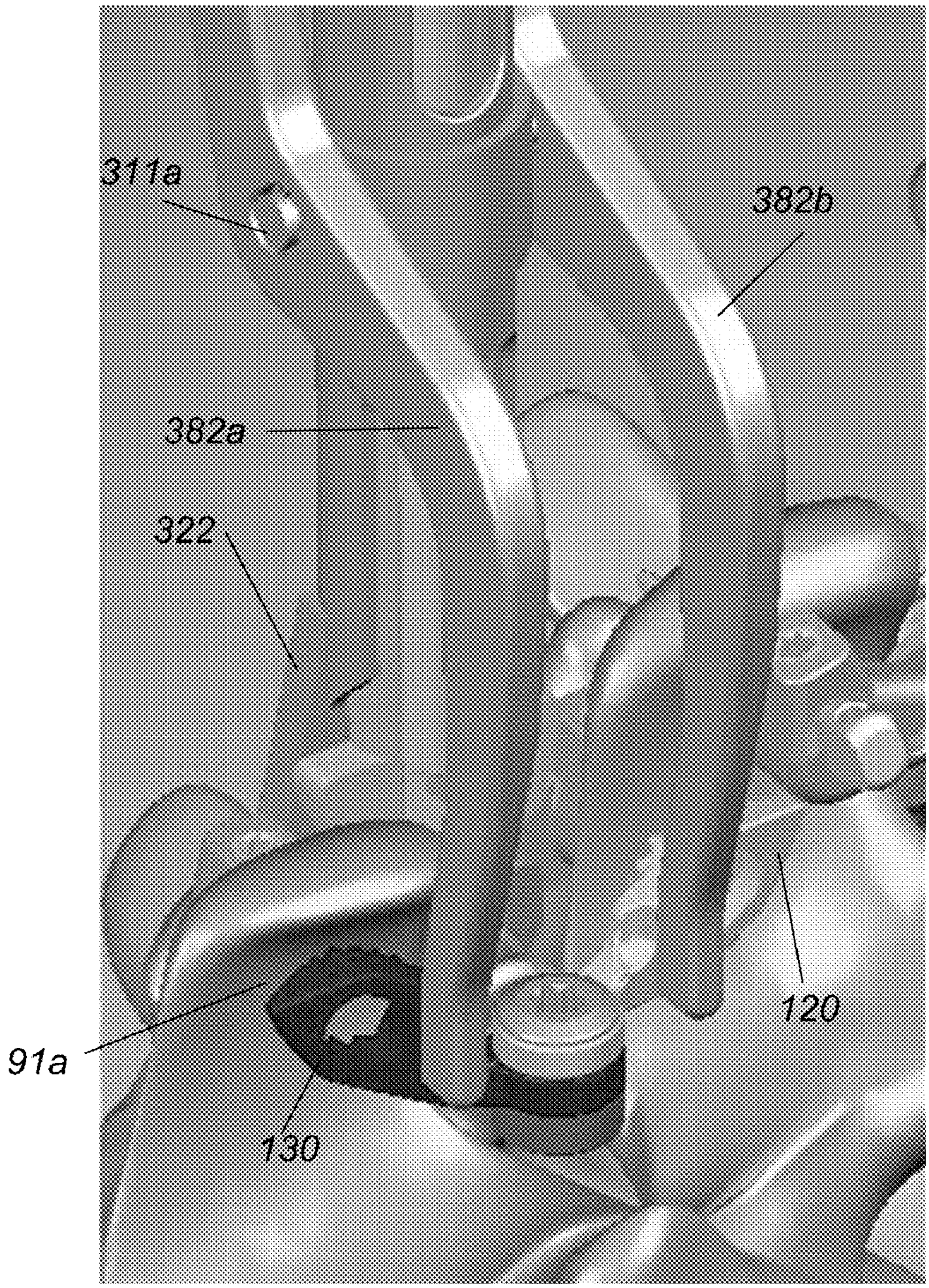

FIG. 17

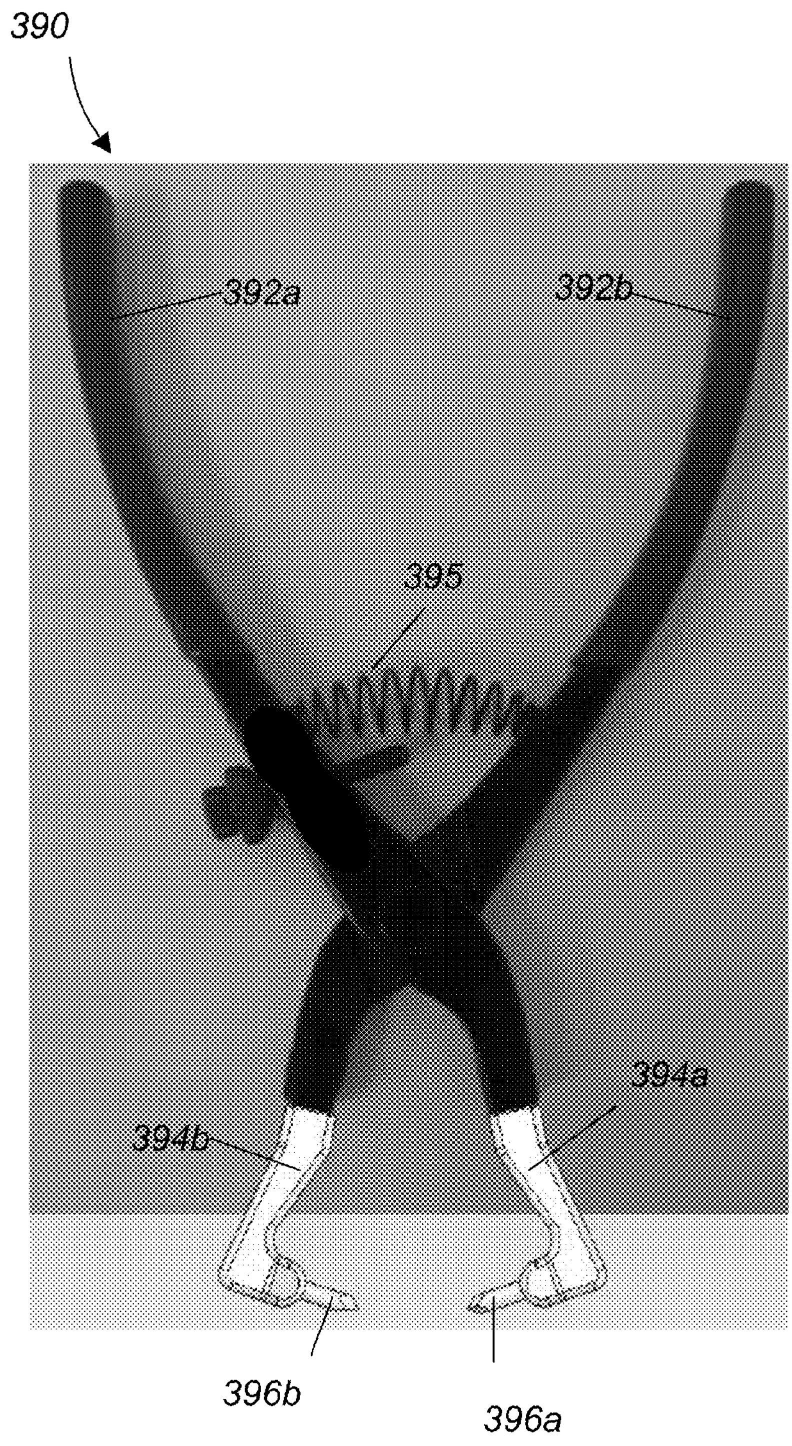

FIG. 18

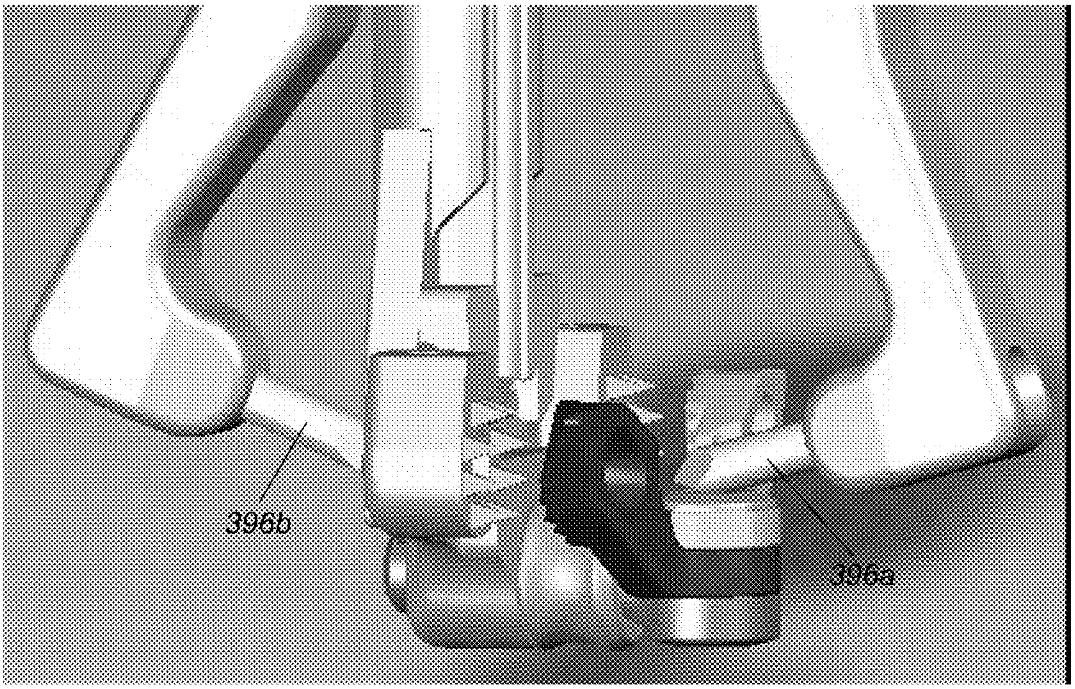

FIG. 19

410

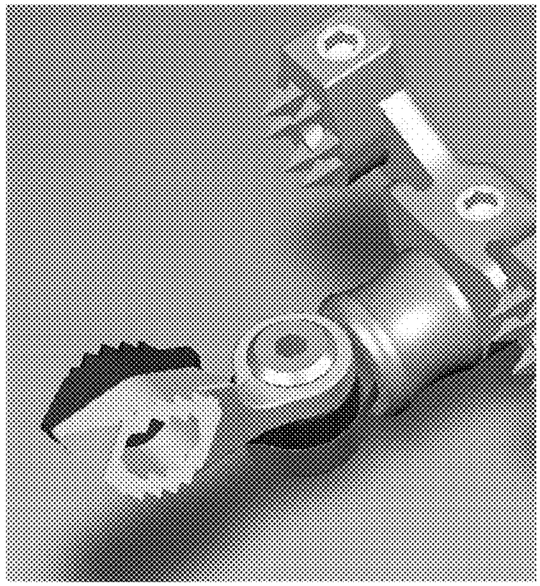

FIG. 20A

420

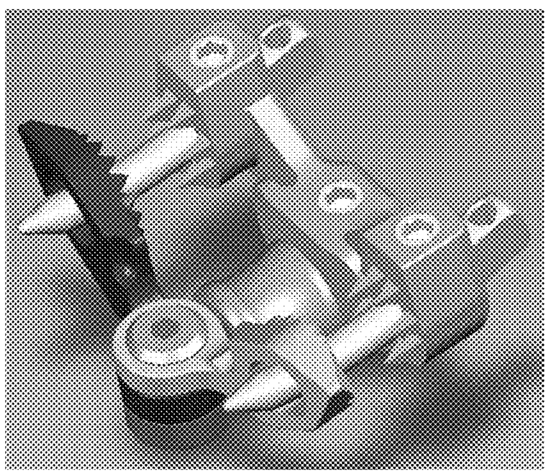

FIG. 20B

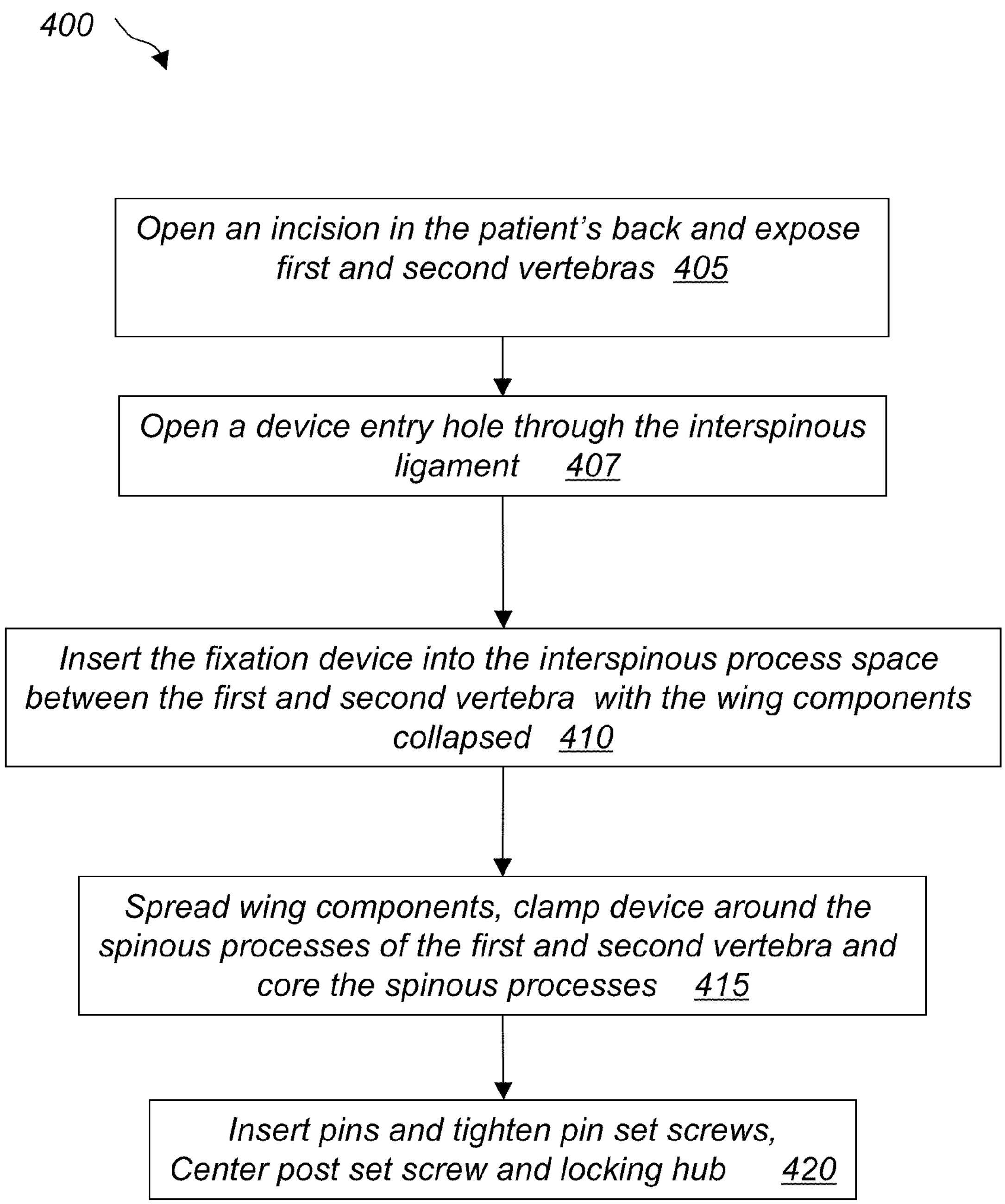
400
Open an incision in the patient's back and expose first and second vertebras 405
Open a device entry hole through the interspinous ligament 407
Insert the fixation device into the interspinous process space between the first and second vertebra with the wing components collapsed 410
Spread wing components, clamp device around the spinous processes of the first and second vertebra and core the spinous processes 415
Insert pins and tighten pin set screws, Center post set screw and locking hub 420

FIG. 21

SPINOUS PROCESS FIXATION IMPLANT

CROSS REFERENCE TO RELATED CO-PENDING APPLICATIONS

This application claims the benefit of U.S. provisional application Ser. No. 61/121,955 filed Dec. 12, 2008 and entitled "IMPROVED SPINOUS PROCESS FIXATION IMPLANT", the contents of which are expressly incorporated herein by reference.

This application is also a continuation in part of U.S. utility application Ser. No. 11/609,418 filed Dec. 12, 2006 and entitled "SPINOUS PROCESS FIXATION IMPLANT", the contents of which are expressly incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to a system and a method for spinal stabilization through an implant, and more particularly to spinal stabilization through attachment of an improved implant to the spinous processes along one or more vertebras.

BACKGROUND OF THE INVENTION

The human spine comprises individual vertebras **30** (segments) that are connected to each other to form a spinal column **29**, shown in FIG. **1**. Referring to FIGS. **1**B and **1**C, each vertebra **30** has a cylindrical bony body (vertebral body) **32**, three winglike projections (two transverse processes **33**, **35** and one spinous process **34**), left and right facet joints **46**, lamina **47**, left and right pedicles **48** and a bony arch (neural arch) **36**. The bodies of the vertebrae **32** are stacked one on top of the other and form the strong but flexible spinal column. The neural arches **36** are positioned so that the space they enclose forms a tube, i.e., the spinal canal **37**. The spinal canal **37** houses and protects the spinal cord and other neural elements. A fluid filled protective membrane, the dura **38**, covers the contents of the spinal canal. The spinal column is flexible enough to allow the body to twist and bend, but sturdy enough to support and protect the spinal cord and the other neural elements. The vertebras **30** are separated and cushioned by thin pads of tough, resilient fiber known as inter-vertebral discs **40**. Disorders of the spine occur when one or more of the individual vertebras **30** and/or the inter-vertebral discs **40** become abnormal either as a result of disease or injury. In these pathologic circumstances, fusion of adjacent vertebral segments may be tried to restore the function of the spine to normal, achieve stability, protect the neural structures, or to relief the patient of discomfort.

Several spinal fixation systems exist for stabilizing the spine so that bony fusion is achieved. The majority of these fixation systems utilize rods that attach to screws threaded into the vertebral bodies or the pedicles **48**, shown in FIG. **3**C. In some cases component fixation systems are also used to fuse two adjacent vertebral segments. This construction usually consists of two longitudinal components that are each placed laterally to connect two adjacent pedicles of the segments to be fused. This system can be extended along the sides of the spine by connecting two adjacent pedicles at a time similar to the concept of a bicycle chain. Current component fixation systems are basically designed to function in place of rods with the advantage of allowing intersegmental fixation without the need to contour a long rod across multiple segments. Both the plating systems and the rod systems add bulk along the lateral aspect of the spine limits access to the pars and transverse processes for decortication and placement of bone graft. In order to avoid this limitation many surgeons decorticate before placing the rods, thereby increasing the amount of blood loss and making it more difficult to maintain a clear operative field. Placing rods or components lateral to the spine leaves the center of the spinal canal that contains the dura, spinal cords and nerves completely exposed. In situations where problems develop at the junction above or below the fused segments necessitating additional fusion, the rod fixation system is difficult to extend to higher or lower levels that need to be fused. Although there are connectors and techniques to lengthen the fixation, they tend to be difficult to use and time consuming.

Accordingly, there is a need for a spinal stabilization device that does not add bulk to the lateral aspect of the spine and does not limit access to the pars and transverse processes for decortication and placement of bone graft.

SUMMARY OF THE INVENTION

In general, in one aspect, the invention features an implantable assembly for stabilization of two adjacent spinous processes in a spinal column, including an elongated component extending along a first axis, a first pivoting wing, a second pivoting wing and a spacer extending along a second axis. The second axis is perpendicular to the first axis and the spacer is placed between the elongated component and the first and second pivoting wings. The first and second pivoting wings are arranged opposite to the elongated component at a distance defined by the spacer width and comprise inner surfaces that face an inner surface of the elongated component. The first and second pivoting wings pivot around a third axis, which is perpendicular to the first axis and the second axis. A first spinous process is placed and clamped between the first pivoting wing inner surface and a first area of the elongated component inner surface by pivoting the first pivoting wing toward the elongated component. A second spinous process is placed and clamped between the second pivoting wing inner surface and a second area of the elongated component inner surface by pivoting the second pivoting wing toward the elongated component.

Implementations of this aspect of the invention may include one or more of the following features. The assembly further includes first and second pins. The first pin is dimensioned to pass through three concentrically aligned through-bore openings formed in the first pivoting wing, the first spinous process and the first area of the elongated component, respectively. The second pin is dimensioned to pass through three concentrically aligned through-bore openings formed in the second pivoting wing, the second spinous process and the second area of the elongated component, respectively. The first and second areas of the elongated component inner surface and the first and second wing inner surfaces comprise protrusions designed to frictionally attach to surfaces of the first and second spinous processes, respectively. The assembly further includes a third pin dimensioned to pass through two concentrically aligned through-bore openings formed in the spacer along the second axis and in the center of the elongate component, respectively. The third pin comprises a ring extending from a first end and the ring defines a through opening extending along the third axis. Each of the pivoting wings comprises a ring extending from a first end of each pivoting wing and the pivoting wing rings are oriented concentric with the third pin ring along the third axis. The assembly may further include an elongated bolt dimensioned to pass through the pivoting wing rings and the third pin ring. The elongated bolt comprises threads formed at a portion of the bolt, and the threads are dimensioned to engage a nut after

the bolt exits the rings. The third pin ring comprises radially extending grooves that interlock with radially extending grooves formed in the pivoting wing rings. The spacer is dimensioned to fit between the first and second spinous processes and comprises an outer surface that is sculpted to conform to the shape of the spinous processes. The assembly may further include first, second and third locking elements for securing the first, second and third pins, respectively, to the elongated component. The locking elements comprise a setscrew dimensioned to engage threads formed in openings formed in the elongated component, and the openings extend along an axis perpendicular to the first and second axes. The spacer comprises fenestrations configured to receive bone growth promoting material. The spacer may be an integral extension of the elongated component.

In general, in another aspect, the invention features a method for stabilizing two adjacent spinous processes in a spinal column including the following. Providing an elongated component extending along a first axis. Providing first and second pivoting wings. Providing a spacer extending along a second axis, wherein the second axis is perpendicular to the first axis. Placing the spacer between the elongated component and the first and second pivoting wings. Arranging the first and second pivoting wings opposite to the elongated component and placing them at a distance defined by the spacer width so that inner surfaces of the pivoting wings face an inner surface of the elongated component. Pivoting the first and second pivoting wings around a third axis, which is perpendicular to the first axis and the second axis. Placing a first spinous process and clamping it between the first pivoting wing inner surface and a first area of the elongated component inner surface. Placing a second spinous process and clamping it between the second pivoting wing inner surface and a second area of the elongated component inner surface.

Among the advantages of this invention may be one or more of the following. The assembly stabilizes vertebras by attaching components to the spinous processes of the vertebras. This stabilization device does not add bulk to the lateral aspect of the spine and does not limit access to the pars and transverse processes for decortication and placement of bone graft. The compact form of the implant assembly allows it to be implanted via mini-open surgery. The device form conforms to the local vertebral anatomy. In particular, the adjustable winged plates fit to the spinous process contour. The device may be used alone or as adjunct to facet or pedicle screw systems. It provides multi-level (i.e., multi-vertebra) fusion through replication of the basic unit. The device is securely attached to the spinous processes via the center post, individual wings and pins. The fenestrated spacer enables application of graft material and promotes bone growth through the device.

The details of one or more embodiments of the invention are set forth in the accompanying drawings and description below. Other features, objects and advantages of the invention will be apparent from the following description of the preferred embodiments, the drawings and from the claims

BRIEF DESCRIPTION OF THE DRAWINGS

Referring to the figures, wherein like numerals represent like parts throughout the several views:

FIG. **1**A is a side view of the human spinal column;

FIG. **1**B is an enlarged view of area A of FIG. **1**A;

FIG. **1**C is an axial cross-sectional view of a lumbar vertebra;

FIG. **2** is a posterior view of a portion of the spine with a first embodiment of a spinous process fixation implant according to the present invention affixed thereto;

FIG. **3** is a front view of the spinous process fixation implant of FIG. **2**;

FIG. **4** is a back view of the spinous process fixation implant of FIG. **2**;

FIG. **5** is a left side perspective view of the elongated component **110** of the fixation implant of FIG. **2**;

FIG. **5**A is a front view of another embodiment of the elongated component **110** with the integrated spacer **140**;

FIG. **6** is a perspective view of the spinous process implant of FIG. **2**;

FIG. **7** is an exploded view of the pivoting wing components of the fixation implant of FIG. **2**;

FIG. **7**A is a detailed view of ring **134** of FIG. **7**;

FIG. **8**A is a perspective view of the spacer **140** of the fixation implant of FIG. **2**;

FIG. **8**B is a perspective view of the center pin **150** of the fixation implant of FIG. **2**;

FIG. **8**C is a perspective view of pin **160***a* of the fixation implant of FIG. **2**;

FIG. **9** is a front view of another embodiment of the spinous process fixation implant;

FIG. **10** is a perspective view of a dilator tool;

FIG. **11** is a perspective view of an inserter tool;

FIG. **12** is a detailed view of a grasper attachment used in connection with the inserter tool of FIG. **11**;

FIG. **13** is a perspective view of a wing spreader tool;

FIG. **14**A is a detailed view of the wing spreader tool of FIG. **13** in the closed position;

FIG. **14**B is a detailed view of the wing spreader tool of FIG. **13** in the open position;

FIG. **15** is a perspective view of a clamps assembly used in connection with the inserter tool of FIG. **11**;

FIG. **16** and FIG. **17** are detailed views of the clamps attachment of FIG. **15**;

FIG. **18** is a schematic view of the trocar-tipped cortical punch tool;

FIG. **19** is a detailed view of the trocar-tipped cortical punch tool;

FIG. **20**A depicts the fixation device of FIG. **2** with the wing components collapsed;

FIG. **20**B depicts the fixation device of FIG. **2** with the wing components spread; and

FIG. **21** depicts the method of implanting the fixation device of FIG. **2**.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a system and a method for an improved spinous process fixation implant.

Referring to FIG. **2**, spinous process fixation assembly **100** stabilizes two adjacent vertebras **92**, **94** of the human spine by engaging and locking their spinous processes **90***a* and **90***b*, respectively. Referring to FIG. **3**, spinous process fixation assembly **100** includes an elongate component **110**, top and a bottom pivoting wing components **120**, **130** and a spacer **140**. Top and bottom pivoting wing components **120**, **130** are arranged opposite to component **110** at a distance **155** set by the length of spacer **140**. Top and bottom pivoting wing components **120**, **130** pivot around axis **180** (shown in FIG. **6**) independent from each other, forming angles **162**, **164** with component **110**, respectively. The pivoting motion of components **120**, **130** along directions **144***a*, **144***b* and **146***a*, **146***b*, moves them close to or away from the elongated component **110**, as shown in FIG. **3** and results in clamping or unclamp-

ing of the spinous processes **90**_a_, **90**_b_ between the elongated component **110** and pivoting wing components **120** and **130**, respectively. The clamping of the spinous processes **90**_a_, **90**_b_ stabilizes the positions of the corresponding vertebras **92**, **94** and prevents them from moving relative to each other.

Referring to FIG. **5**, elongated component **110** includes a body **112** having a top end **113**_a_, a bottom end **113**_b_, left side **118** and right side **117**. Top and bottom ends **113**_a_, **113**_b_ include side openings **116**_a_, **116**_b_ respectively, extending from the left side **118** through to the right side **117**. Side openings **116**_a_, **116**_b_ are dimensioned to receive pins **160**_a_, **160**_b_, respectively, shown in FIG. **3**. Pins **160**_a_, **160**_b_ pass through openings formed in the spinous processes **90**_a_, **90**_b_, respectively, and then pass through openings **122**, **132** formed in the pivoting wing components **120**, **130**, respectively, shown in FIG. **6**, thereby providing additional fixation of the spinous processes. A portion of the right side surfaces **117** of the top and bottom ends **113**_a_, **113**_b_ includes protrusions **111** designed to frictionally attach onto the left sides of the spinous processes **90**_a_, **90**_b_, respectively. Top and bottom ends **113**_a_, **113**_b_ also include front openings **114**_a_, **114**_b_ respectively, dimensioned to receive post set screws **182**_a_, **182**_b_, for securing the positions of pins **160**_a_, **160**_b_ in the side openings **116**_a_, **116**_b_, respectively. Component **110** also includes a center through side opening **115** extending through the center of body **112** from the left side **118** through to the right side **117**. Center opening **115** is dimensioned to receive a center pin **150** connecting component **110** to pivoting wing components **120** and **130**. A center post set screw **183** is threaded into front opening **114**_c_ having an axis perpendicular to the axis of side opening **115** and secures the position of center pin **150** into the opening **115**. The medial-lateral position of component **110** relative to center pin **150** is adjusted by unlocking post set screw **183**. Left side surface **118** also includes two partial openings **111**_a_, **111**_b_, used to anchor tools for picking up and placing component **110** between the spinous processes **90**_a_, **90**_b_. The front surface of the elongated component **110** also includes partial openings (depressions) **119**_a_, **119**_b_ used to anchor tools for picking up and placing the component.

Referring to FIG. **8**B, center pin **150** includes a cylindrical body **156** having a first end **151**_a_ protruding from the left side of opening **115** and a second end **151**_b_ having a ring **152** attached to it. Axis **180** of ring **152** is oriented perpendicular to the longitudinal axis **158** of the cylindrical body **156**. Ring **152** includes inner threads **154** dimensioned to engage outer threads of a long bolt/locking hub **185**, shown in FIG. **6**. In some embodiments, the front surface of ring **152** includes grooves **159** designed to interlock with grooves **189** formed on the surfaces of rings **134** and **124** of the pivoting wing components, as will be described below. Cylindrical body **156** also includes a depression **153** for receiving the center post set screw **183**. Cylindrical body **156** is dimensioned to pass through a center opening **142** of the spacer component **140**, shown in FIG. **8**A. Spacer **140** is placed between the spinous processes **90**_a_, **90**_b_ and provides cephalocodal support of the spinous processes **90**_a_, **90**_b_. Spacer **140** is shaped and dimensioned to fit the geometry and local anatomy of the spinous processes. In one example, spacer **140** is cylindrically shaped and has a sculpted outer surface **148**, as shown in FIG. **8**A. In particular, spacer **140** has a curved outer surface and the diameter of the cylinder in the center section is smaller than the diameter of the cylinder at the ends. In some embodiments spacer **140** includes fenestrations **145**, shown in FIG. **9**. In other embodiments fenestrations **145** are filled with graft material. The graft material promotes bone growth and provides enhanced fusion. In some embodiments, spacer **140** and the other components of the assembly are coated with hydroxy-apatite coating to promote bone growth. In other embodiments, spacer **140** is fixedly attached to component **110** or is an extension of elongated component **110**, as shown in FIG. **5**A.

Referring to FIG. **7**, top pivoting wing component **120** includes a main body **125** having top and bottom ends **125**_a_, **125**_b_, respectively, and left and right side surfaces **127**, **128**, respectively. A ring **124** extends downward from the bottom end **125**_b_ and has an axis **180**_a_ passing through opening **123** perpendicular to the main axis **191** of component **120**. Top end **125**_a_ includes a through opening **122** extending from the left side to the right side of the component. Opening **122** is dimensioned to receive pin **160**_a_, as shown in FIG. **6**. Similarly, bottom pivoting wing component **130** has a main body **132** having top and bottom ends **135**_a_, **135**_b_, respectively, and left and right side surfaces **137**, **138** respectively. A ring **134** extends upward form the top end **135**_a_ and has an axis **180**_b_ passing through opening **133** perpendicular to the main axis **192** of component **130**. In some embodiments, the front surfaces of rings **124**, **134** and the back surface of ring **124** include grooves **189** designed to interlock with grooves **159** formed in the front surface of ring **152**, as shown in FIG. **7**A. The interlocking of grooves **189** with grooves **159** provides an additional locking mechanism for the attachment of the pivoting wing components **120**, **130** to the center pin **150**. Bottom end **135**_b_ of pivoting wing component **130** includes a through opening **132** extending from the left side to the right side of the component. Opening **132** is dimensioned to receive pin **160**_b_, as shown in FIG. **6**. Surfaces **128** and **138** of components **120**, **130**, include partial openings (depressions) **129**, **139** used to anchor tools for picking up and pivoting components **120**, **130**, respectively, shown in FIG. **6**. Components **110**, **120**, **130** are made of stainless steel, titanium, gold, silver, alloys thereof, or absorbable material and may adjustable lengths.

Referring to FIG. **6**, long bolt/locking hub **185** passes through aligned apertures **123**, **133** of the top and bottom pivoting wing components **120**, **130**, respectively, and is threaded into aperture **154** of the center pin ring **152**. Bolt **185** has a head **181**, a shaft **183** and outer threads **184** formed on the end portion of the shaft **183**. Outer threads **184** engage inner threads in aperture **154** of the center pin ring **152**, in order to hold and secure the three components **120**, **130** and **150** of the assembly **100** together. In other embodiments, a nut (not shown) is attached at the end of the bolt **185** to hold and secure the three components **120**, **130** and **150** of the assembly **100** together. In other embodiments bolt **185** is threaded into the cartilage between the two vertebras to secure components **110**, **120**, **150** together and to attach the assembly **100** onto the spine. Portions of inner surfaces **117**, **127**, **137** of components **110**, **120**, **130**, respectively, have protrusions **111**, **121**, **131**, respectively, that grab and frictionally engage the sides of the spinous processes **90**_a_, **90**_b_, as shown in FIG. **2**. Protrusions **111** may be teeth, serrations, ridges, and other forms of rough surfaces or coatings that produce rough surfaces. The position of pivoting wing components **120**, **130** relative to each other and relative to component **110** is locked with the long bolt **185**. Engaging and locking the spinous process fixation assembly **100** onto spinous processes **90**_a_, **90**_b_, prevents the components **110**, **120** and **130** from moving sidewise or up and down toward or away from each other during spinal movement.

The assembled spinous process fixation assembly **100** is implanted into the patient with the use of instrumentation between the two adjacent spinous processes **90**_a_, **90**_b_, as shown in FIG. **2**. Referring to FIG. **21**, the implantation

process **400** includes the following steps. First, the surgeon makes an incision in the patient's back and exposes the first and second vertebras, **92**, **94** (**405**). Next a dilator **300** (shown in FIG. **10**) is used to open a device entry hole through the interspinous ligament (**407**). Next, the surgeon uses an inserter tool **310** (shown in FIG. **11**) to grasp and insert the device into the interspinous process space between the first and second vertebras **92**, **94** with the wing components **120**, **130** collapsed (as shown in FIG. **20**A) (**410**). The spacer **140** is placed between the spinous processes **90***a*, **90***b* so that the body **112** of the elongated component **110** and the top and bottom pivoting wing components **120**, **130** fall on the lateral sides of the spinous processes **90***a*, **90***b*. One spinous process **90***a* lies between the top portion **113***a* of the body **112** and the top pivoting wing component **120** and the other spinous process **90***b* lies between the bottom portion **113***b* of the body **112** and the bottom pivoting wing component **130**, with their inner surfaces **117**, **127**, **137** facing the lateral surfaces of the spinous processes **90***a*, **90***b*. On each of the inner surfaces **117**, **127**, **137** of the components **110**, **120**, **130**, respectively, the protrusions **111**, **121**, **131** face toward the lateral surface of the adjacent spinous process. Next, the wing components **120**, **130** are spread with the wing spreader **330** (shown in FIG. **13**), the spinous processes **90***a*, **90***b* are clamped between the top **113***a* and bottom **113***b* of the elongated component **110** and the wing components **120** and **130**, respectively, and then the spinous processes **90***a*, **90***b* are cored with the trocar-tipped cortical punch of FIG. **18** (**415**). Next, the top and bottom pins **160***a*, **160***b*, are inserted, the pin set screws **182***a*, **182***b* are tightened and the center post set screw **183** and locking hub **185** are tightened (**420**). The tightening of the set screws **182***a*, **182***b*, **183** and of the locking hub **185**, clamps the protrusions **111**, **121**, **131** into the surfaces of the spinous processes, locks the three components relative to each other and frictionally secures the spinous process fixation assembly **100** onto the spinous processes **90***a*, **90***b* and helps prevent the device from shifting or slipping.

Referring to FIG. **10**, dilator **300** includes an elongated body **304** having a handle **302** at one end and a sharp curved tip **306** at the opposite end. The curved tip end is used to create entry holes through the interspinous ligament without affecting the surrounding anatomy.

Referring to FIG. **11**, inserter **310** includes an elongated tubular body **316**, a handle **312** disposed at the proximal end of the body **316** and a grasper **320** disposed at the distal end of the tubular body **316**. Handle **312** includes a lever **314** used to actuate capturing or releasing of a component via the grasper **320**. Referring to FIG. **12**, grasper **320** includes an outer tubular component **321** and an inner tubular component **325**. Inner tubular component **325** is disposed within the tubular body **316** and outer tubular component **321** is an extension of the tubular body **316**. Outer tubular component **321** includes a grasping element **322** having pins **323***a*, **323***b*. Pins **323***a*, **323***b* are configured to be inserted into partial holes **111***a*, **111***b* of the elongated component **110** during the grasping action. Inner tubular component **325** includes two spread out grasping elements **317***a*, **317***b*. Grasping elements **317***a*, **317***b* are configured to be spaced apart and to be inserted into partial openings (depressions) **119***a*, **119***b* of the elongated body **110** for picking up and placing the entire fixation device **100**. Grasping elements **317***a*, **317***b* are actuated via lever **314**. Tubular body **316** also includes pins **311***a*, **311***b* used to engage clamps **380** and other attachments, shown in FIG. **15**.

Referring to FIG. **14**A and FIG. **14**B a wing spreader **350** includes an outer tubular body **351** having a handle at the proximal end (not shown) and terminating into first spreading element **354**. Wing spreader **350** also includes an inner tubular body **355** disposed within outer tubular body **351** and terminating at a second spreading element **352**. In other embodiments, wing spreader **350** is an attachment that is attached to the side of the tubular component **316** of the inserter **310**, as shown in FIG. **13**. In operation, tubular body **351** is placed over the locking hub **185**, the spreading elements **352**, **354** engage the wing components **130**, **120**, respectively, and open or close them. Spreading elements **352**, **354** include projections **353**, **356**, respectively. Projections **353**, **356** are configured to be inserted into partial openings (depressions) **129**, **139**, formed on surfaces **128** and **138** of components **120**, **130**, respectively. Spreading elements **352**, **354** are configured to be pivoted independent from each other via separate actuator causing the inner and outer tubular bodies **355**, **351** to rotate. A screwdriver is inserted through the inner tubular body **355** for tightening the locking hub **185**.

Referring to FIG. **15**, clamps **380** assemble easily to the inserter **310** by engaging pins **311***a*, **311***b* of the tubular body **316**. Clamps **380** hold the fixation device **100** in place and press the wing components **120**, **130** against the first lateral surfaces **91***a* of the spinous processes, while the grasping element **322** of the inserter **310** presses the elongated component **110** against the opposite lateral surfaces **91***b* of the spinous processes, as shown in FIG. **17** and FIG. **16**. Clamps **380** include first and second parallel arranged clamping elements **381***a*, **381***b*, terminating into prongs **382***a*, **382***b*. The proximal ends of the clamping elements include handles **383***a*, **383***b* that engaged loops **313***a*, **313***b* formed in the handle **312** of the inserter **310**.

Referring to FIG. **18** a trocar-tipped cortical punch **390** includes disposable tips **396***a*, **396***b* at the end of the prongs **394***a*, **394***b*. The disposable tips **396***a*, **396***b* are used to start the pin holes through the cortical bone of the spinous process simultaneously on both sides **91***a*, **91***b* of the spinous process, as shown in FIG. **19**. Once the holes are punched through the spinous processes, pins **160***a*, **160***b* are inserted through the top **113***a* and bottom **113***b* portions of the elongated component **110**, the spinous processes and the wing components **120**, **130**. In other embodiments cortical punch **390** includes one tip **396***a* and the end of prong **394***a* and an opening at the end of prong **394***b* (not shown). The opening at the end of prong **394***b* is dimensioned to receive tip **396***a*, when the prongs **394***a*, **394***b* are closed.

Other embodiments are within the scope of the following claims. For example, vertebras **92** and **94** may be any two vertebras, including lumbar L1-L5, thoracic T1-T12, cervical C1-C7 or the sacrum. The fixation assembly **100** may extend along multiple vertebras. The fixation assembly **100** of FIG. **3** may be also configured as a mirror image of the structure in FIG. **3**, with the pivoting wing components **120**, **130** located on the left side and the elongated component **110** located on the right side of the FIG. **3**. The elongated component **110**, and the top and bottom pivoting wing components **120**, and **130**, respectively, may have adjustable lengths. Elongated component **110** and spacer **140** may be incorporated into one component or may be fixedly attached to each other. Center post set screw **183** may be also used to secure component **110** onto a location of either vertebra **92**, **94**. Pins **160***a*, **160***b* may not be included in the assembly **100**. Spacer **140** may not be a separate component. Spacer **140** may be an integral part of body **156**. Spacer **140** may have straight (non-curved) outer surface **148**.

Several embodiments of the present invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit

and scope of the invention. Accordingly, other embodiments are within the scope of the following claims.

What is claimed is:

1. An implantable assembly for stabilization of two adjacent spinous processes in a spinal column, comprising:

an elongated component extending along a first axis;

a first pivoting wing;

a second pivoting wing;

a spacer extending along a second axis, wherein said second axis is perpendicular to said first axis and wherein said spacer is placed between said elongated component and said first and second pivoting wings;

a central pin dimensioned to pass through two concentrically aligned through-bore openings formed in said spacer along said second axis and in the center of said elongate component, respectively, and wherein said central pin comprises a ring extending from a first end and wherein said ring defines a through opening extending along a third axis;

wherein said first and second pivoting wings are arranged opposite to said elongated component at a distance defined by said spacer width and comprise inner surfaces that face an inner surface of said elongated component;

wherein said first and second pivoting wings pivot around said third axis, wherein said third axis is perpendicular to said first axis and said second axis; and

wherein a first spinous process is placed and clamped between said first pivoting wing inner surface and a first area of said elongated component inner surface by pivoting said first pivoting wing toward said elongated component and a second spinous process is placed and clamped between said second pivoting wing inner surface and a second area of said elongated component inner surface by pivoting said second pivoting wing toward said elongated component.

2. The assembly of claim **1** further comprising first and second pins and wherein said first pin is dimensioned to pass through three concentrically aligned through-bore openings formed in said first pivoting wing, said first spinous process and said first area of said elongated component, respectively, and wherein said second pin is dimensioned to pass through three concentrically aligned through-bore openings formed in said second pivoting wing, said second spinous process and said second area of said elongated component, respectively.

3. The assembly of claim **1** wherein said first and second areas of said elongated component inner surface and said first and second wing inner surfaces comprise protrusions designed to frictionally attach to surfaces of said first and second spinous processes, respectively.

4. The assembly of claim **3** further comprising first, second and third locking elements for securing said first, second and central pins, respectively, to said elongated component and wherein said locking elements comprise a set screw dimensioned to engage threads formed in openings formed in said elongated component, and wherein said openings extend along an axis perpendicular to said first and second axes.

5. The assembly of claim **1** wherein each of said pivoting wings comprise a ring extending from a first end of each pivoting wing and wherein said pivoting wing rings are oriented and placed concentric with said central pin ring along said third axis.

6. The assembly of claim **5** further comprising an elongated bolt dimensioned to pass through said pivoting wing rings and said central pin ring and wherein said elongated bolt comprises threads formed at a portion of said bolt, and said threads are dimensioned to engage a nut after the bolt exits said rings.

7. The assembly of claim **5** wherein said central pin ring comprises radially extending grooves that interlock with radially extending grooves formed in said pivoting wing rings.

8. The assembly of claim **1**, wherein said spacer is dimensioned to fit between said first and second spinous processes and comprises an outer surface that is sculpted to conform to the shape of said spinous processes.

9. The assembly of claim **1** wherein said spacer comprises fenestrations configured to receive bone growth promoting material.

10. The assembly of claim **1** wherein said spacer is an integral extension of said elongated component.

11. A method for stabilizing two adjacent spinous processes in a spinal column, comprising:

providing an elongated component extending along a first axis;

providing a first pivoting wing;

providing a second pivoting wing;

providing a spacer extending along a second axis, wherein said second axis is perpendicular to said first axis;

providing a central pin dimensioned to pass through two concentrically aligned through-bore openings formed in said spacer along said second axis and in the center of said elongate component, respectively, and wherein said central pin comprises a ring extending from a first end and wherein said ring defines a through opening extending along a third axis;

placing said spacer between said elongated component and said first and second pivoting wings;

arranging said first and second pivoting wings opposite to said elongated component and placing them at a distance defined by said spacer width so that inner surfaces of said pivoting wings face an inner surface of said elongated component;

pivoting said first and second pivoting wings around said third axis, wherein said third axis is perpendicular to said first axis and said second axis;

placing a first spinous process and clamping it between said first pivoting wing inner surface and a first area of said elongated component inner surface; and

placing a second spinous process and clamping it between said second pivoting wing inner surface and a second area of said elongated component inner surface.

12. The method of claim **11** further comprising providing first and second pins, and passing said first pin through three concentrically aligned through-bore openings formed in said first pivoting wing, said first spinous process and said first area of said elongated component, respectively, and passing said second pin through three concentrically aligned through-bore openings formed in said second pivoting wing, said second spinous process and said second area of said elongated component, respectively.

13. The method of claim **12** wherein said first and second areas of said elongated component inner surface and said first and second wing inner surfaces comprise protrusions designed to frictionally attach to surfaces of said first and second spinous processes, respectively.

14. The method of claim **11** wherein each of said pivoting wings comprise a ring extending from a first end of each pivoting wing and wherein said pivoting wing rings are oriented concentric with said central pin ring along said third axis.

15. The method of claim **14** further comprising providing an elongated bolt and passing it through said pivoting wing rings and said central pin ring and wherein said elongated bolt

comprises threads formed at a portion of said bolt, and said threads are dimensioned to engage a nut after the bolt exits said rings.

16. The method of claim **11**, wherein said spacer is dimensioned to fit between said first and second spinous processes and comprises an outer surface that is sculpted to conform to the shape of said spinous processes.

17. The method of claim **16** further comprising providing first, second and third locking elements for securing said first, second and central pins, respectively, to said elongated component and wherein said locking elements comprises a set screw dimensioned to engage threads formed in openings formed in said elongated component, wherein said openings extend along an axis perpendicular to said first and second axes.

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